CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 16, 2003.

Richard C. Salfelder, Reg. No. 51,127

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Richard T. Allen et al.

Serial No. 09/848,819

Filed: May 3, 2001

Continuation of U.S. Serial No. 08/881,059

For: STENT WITH REINFORCED STRUTS AND BIMODAL DEPLOYMENT

Examiner: W. Matthews

Group Art Unit: 3738

Client ID/Matter No. ACS 57527 (1201C)

Date: June 16, 2003

DECLARATION UNDER 37 C.F.R. § 1.131

We, RICHARD T. ALLEN and DANIEL L. COX, declare as follows:

1. We are co-inventors of the subject matter of the above-identified application.

2. We have been informed that U.S. Patent No. 5,868,781 to Killion, filed October 22, 1996 has been cited as a prior art reference against the present application.

3. We invented the claimed subject matter prior to October 22, 1996. Attached as Exhibit A is the invention disclosure form dated prior to October 22, 1996 which includes the drawings that depict the claimed stent and which is the subject matter of the pending claims. The Invention Disclosure Form was signed by us and by a witness

prior to October 22, 1996. The dates on the Invention Disclosure Form have been redacted.

4. We worked diligently on the development of the claimed invention from the time just before October 22, 1996 until the filing of the present application on May 3, 2001.

5. All of the work relating to the claimed subject matter was conducted in the United States at Santa Clara, California.

As the persons signing below, we hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with full knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title XVIII of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

DATE: June 5, 2003

Richard T. Allen
RICHARD T. ALLEN

DATE: June 5, 2003

Daniel L. Cox
DANIEL L. COX

15283.1

CONFIDENTIAL & PRIVILEGED

ADVANCED CARDIOVASCULAR SYSTEMS, INC.

INVENTION DISCLOSURE FORM

For Legal Department Use Only

To: Legal Department

cc: Motasim Sirhan

Docket No.:
Date Assigned:

Submitter: Daniel Cox and Richard Allen

This is a form for disclosing ideas and inventions to the ACS Legal Department for patent consideration. This form may be used before experimental work has been done. While some of the requested information may not be available at this time, include as much information as you can about the invention. Attach additional sheets if necessary, and sign and date each sheet. Additional information will be requested later.

1. DESCRIPTIVE TITLE OF THE INVENTION
Stent with Reinforced Struts and Bimodal Deployment

2. DESCRIPTION AND USE - (a) Describe the invention in as much detail as possible, and include a description of a working prototype, if any. Write your description using reference numerals placed on a drawing. Point out and explain relationship with associated equipment. (b) How is the invention used? (c) How does it relate to present or potential commercial products of ACS or others? (d) State the significance of the invention, and any problems it is intended to solve. Please supplement when possible by attaching sketches, engineering drawings, pages from lab books, photographs, and the like.

The devices described are endovascular stents which would be used in a manner similar to the current ACS Multilink. All of the devices described could be cut from a tube using a laser as a convenient manufacturing method.

Dan K Cox

Richard Allen

EXHIBIT A

The area of peak stress in most zigzag type stent designs is at or near the apex of the curve, 1, at the ends of the zigzags (Figure 1). The invention is a method for reinforcing this area with an additional member, 2, which is attached to each side of the the zigzags away from the apex of the main curve, 1. This member can be constructed in a variety of ways, some examples of which are shown in Figure 1. The strut width of the main curve, 1, in relation to the width and geometry of the reinforcing member, 2, would be experimentally determined for each configuration to distribute the stress between the two members. This would probably vary with the material chosen for the stent.

A complete stent could be constructed from this geometry in a variety of ways. Two examples are drawn in Figures 2 and 3. The stent in Figure 2 uses the reinforcing geometry of Figure 1C as the base pattern. This pattern connects the reinforcing member, 3, to the next ring at 4. When deployed this stent will probably shorten somewhat. The stent in Figure 3 is based on the geometry in Figure 1J. This base patterns are connected similar to that of the ACS Multilink.

The length and width of the reinforcing member could be chosen to create a bimodal deployment. This is illustrated in Figure 4 based on the stent in Figure 3. The first mode is shown in Figure 4A in which the reinforcing member, 5, straightens and locks into position. The reinforcing member in this configuration provides substantial strength and stiffness to the stent. As the stent is expanded further, the strut, 6, bends at point 7 until it is aligned with the circumference of the stent as shown in Figure 4B. At this point the stent is fully deployed to its maximum diameter. Note that the reinforcing member and stent could be made to deploy without 2 distinct modes. This behavior is controlled by the force required to bend the strut, 6, at point 7, compared to the force require to bend and open the reinforcing member. This can be controlled by the relative widths and lengths of the various members.

3. PROJECTED GENERIC SCOPE - Describe the invention in terms of the broadest generic scope which you expect will be operable (e.g. if a machine or article, describe alternate type and sizes of materials for construction, etc.; if a process, describe alternate manufacturing conditions, etc.).

Should apply to any of the standard stent materials like stainless steel, NiTi, tantalum, Pt/Ir, etc. It should also work in any appropriate diameter tubular structure in the body which may benefit from a stent. The designs shown are all balloon expandable by a standard angioplasty catheter.

Donald A Cox

Richard Allen

4. REFERENCES - (a) Has a literature search been made? (b) List and, if possible, attach copies of all literature, publications, patents, and patent applications of which you are aware relating to the invention. See section in Guidelines for Completing Invention Disclosure Form concerning obligation of disclosure.

No literature search has been done.

5. DISCLOSURE OR USE - (a) Is the invention known to anyone outside of ACS ? (b) Has the invention been used outside ACS ? (c) What is the current stage of development of the invention ? (d) Are there plans to disclose or use the invention outside of ACS ?

The inventions have not been shown to anyone outside ACS. The current designs are in the proof of concept phase and no prototypes have been produced yet. There are no current plans to disclose this information.

Submitters Daniel L. Cox _____
Print and Sign Date

Richard Allen Rutan
_____

Read and Understood the completed Invention Disclosure Form (not a Submitter)

Richard J Rapoza _____
Print and Sign Date

_____

PLEASE PRINT NAME OF DIRECTOR AND MANAGER

Director Motasim Sirhan Manager Richard Rapoza

Director _____ Manager _____

Director _____ Manager _____

Daniel G

Richard Allen

Figure 1

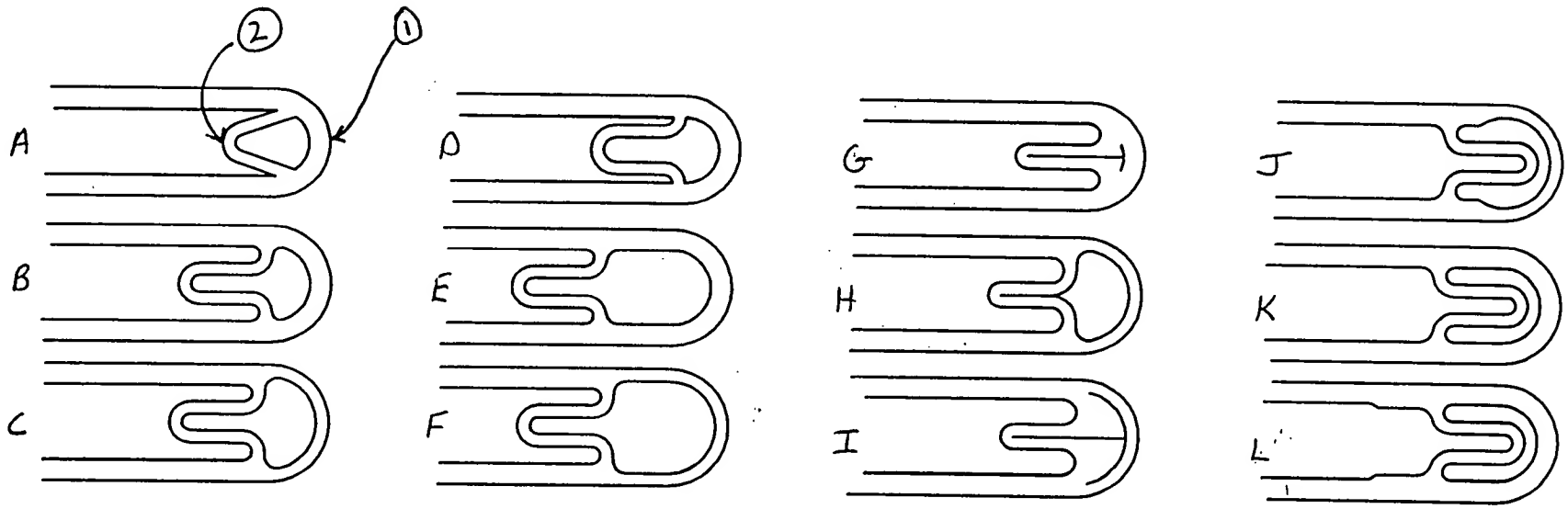


Figure 2

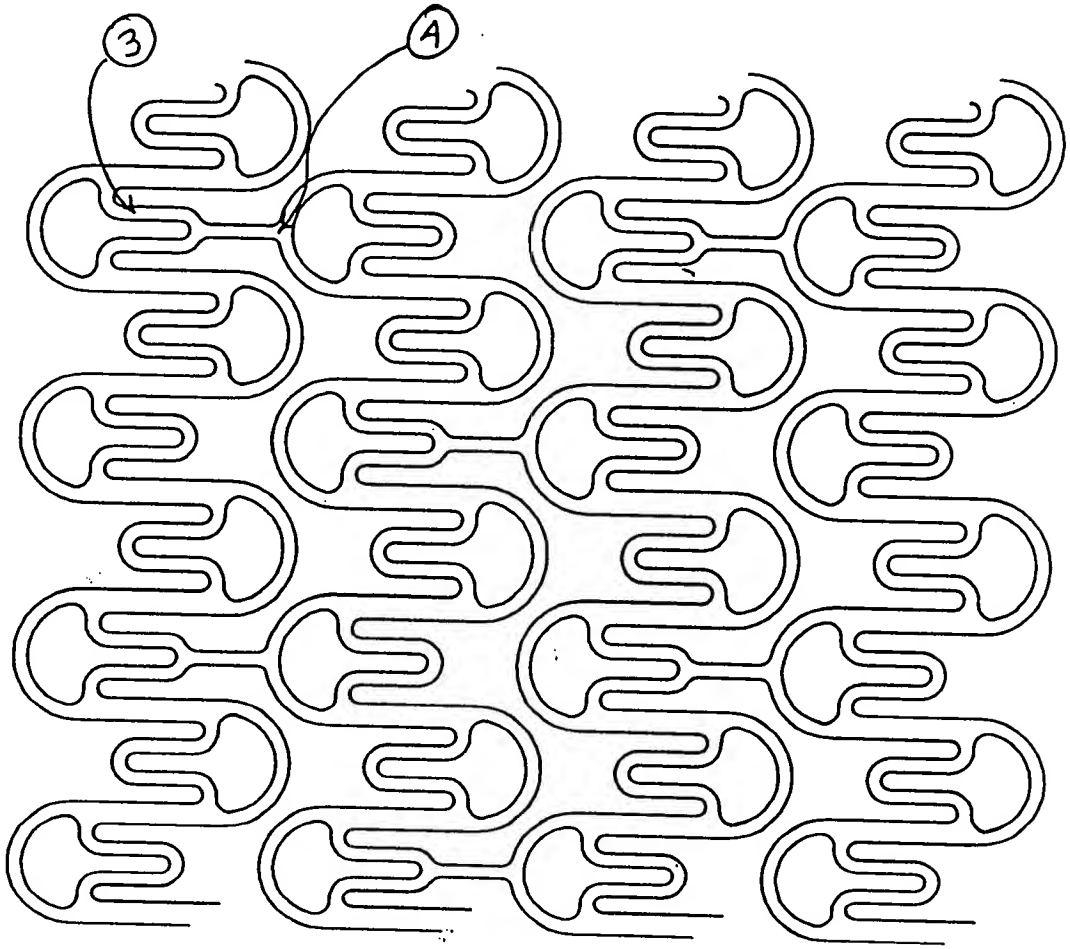


Figure 3

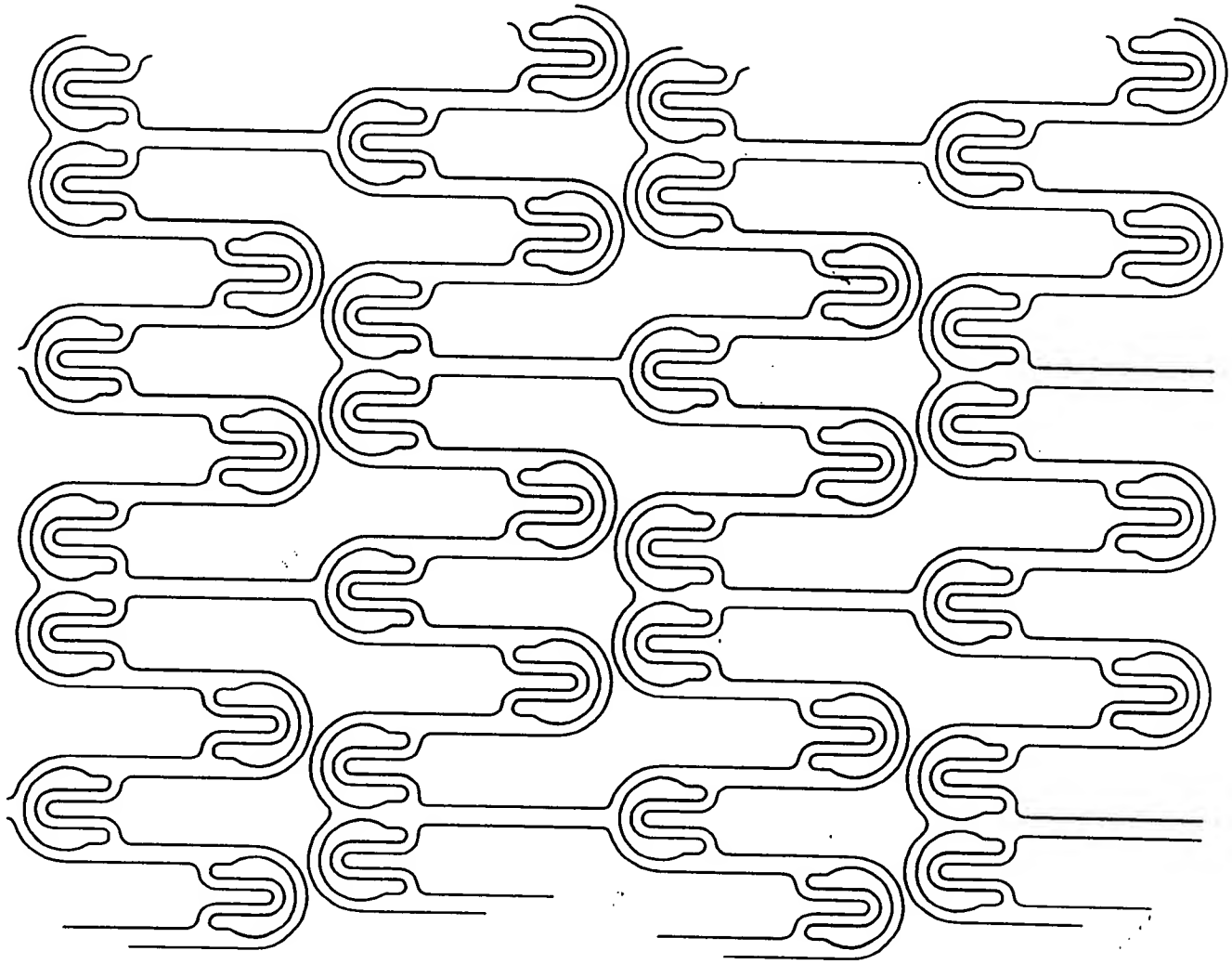
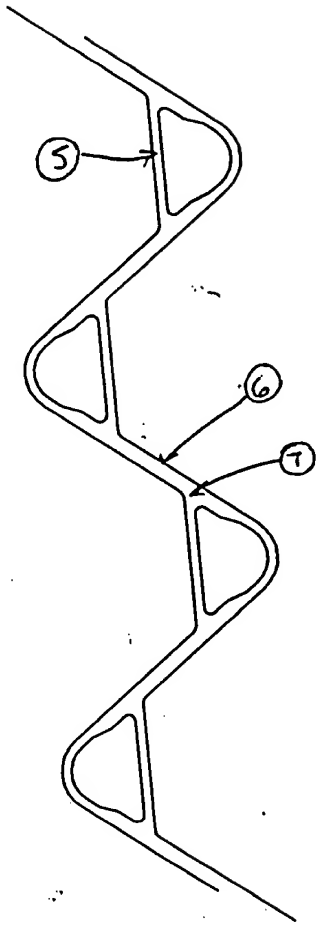
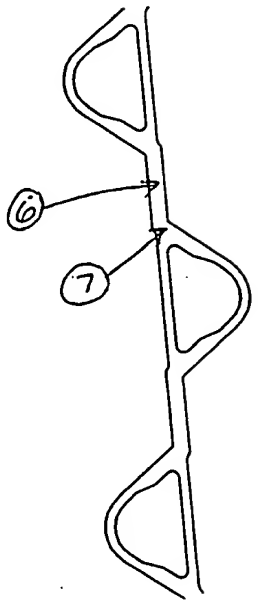


Figure 4



A



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